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Confirmation No.: 7223
Art Unit: 1614

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REMARKS

Applicant respectfully requests the Examiner to enter the above amendments and to reconsider the objection and rejection in view of the following remarks and amendments.

Status of Claims

Claims 1 to 13 will be pending after entry of the present amendment. Claims 1, 2, 5, and 6 are being amended; and Claims 7 to 13 are being added. Claims 1 to 6 have been rejected under 35 U.S.C. §112, first paragraph.

Amendment

The specification is being amended to clarify in the title and second paragraph of the specification that the invention is related to treating, preventing, inhibiting, and ameliorating gastrointestinal conditions such as irritable bowel syndrome, colitis and Crohn's Disease. It is noted that the term "hyperactive gastric motility" is meant to include hyperactive motility in the intestines. Support for these amendments are found, for example, on page 11, line 16 to page 12, line 5; page 13, lines 5 to 19; and page 19, lines 5 to 20.

The specification is also being amended to provide a new Abstract Of The Disclosure that relates to the compounds of the formula on page 7 of the specification.

Claim 1 is being amended to recite a method of treating or inhibiting a "gastrointestinal condition associated with at least one of irritable bowel syndrome, Crohn's Disease, colitis, diarrhea, abdominal pain associated with diarrhea, postprandial urgency, postprandial accentuation of diarrhea or abdominal pain, or nonulcer dyspepsia." This amendment is supported by the specification, for example, at page 11, lines 15 to 30.

Claim 2 is being amended for editorial reasons to delete "treatment".

Claims 5 and 6 are being amended to replace "hyperactive gastric motility" with "gastrointestinal condition" for consistency with Claim 1.

Claims 7 to 13 are new and are supported by the specification for example at:

Claim	Example of Support in Specification
7 to 9	page 1, lines 24 to 26, page 11, lines 19 to 29
10 to 13	page 14, lines 14 to 20

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No new matter is added by the amendments to the specification or claims.

Objection of Disclosure

The disclosure has been objected to because it is "unclear whether Applicant intends to be limited to gastric motility, i.e., motility only associated with the stomach, or gastrointestinal motility." Applicant has amended the title and second paragraph of the specification to clarify that the invention is not limited to motility only associated with the stomach. In this regard, on page 1, line 12, "gastric tissues" has been changed to "gastrointestinal tissues", and on page 1, line 15, Applicant has clarified that "hyperactive gastric motility" is a gastrointestinal condition. The title has also been amended to clarify that the invention generally provides methods for treating gastrointestinal conditions.

In view of the amendments being made to the specification, Applicant respectfully requests that this objection be withdrawn.

Rejection Under Section 112

Claims 1 to 6 have been rejected under Section 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The office action makes reference to the factors in In re Wands, 8 USPQ2d 1400 and concludes that "[t]he instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice the instant invention without resorting to undue experimentation." Applicant respectfully traverses this rejection as the specification contains extensive teachings to enable any person skilled in the art to make and use the claimed invention without undue experimentation.

Enablement under Section 112, first paragraph requires that the specification teach those skilled in the art how to make and use the invention without undue experimentation. *Atlas Powder Co. v. E.I. duPont de Nemours & Co.*, 750 F.2d 1569, 1576 (Fed. Cir. 1984). Applicant has fully complied with this legal standard. For example, Applicant fully describes the compounds useful for carrying out the claimed invention (*see e.g.*, page 6, line 23 to page 11, line 5). Additionally, this description of compounds includes examples of specific compounds that fall under the genus described on page 7 for one skilled in the art to use. Moreover, Applicant describes how the compounds useful in the present invention can be synthesized by

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incorporating by reference U.S. Patent No. 5,565,483 (*see e.g.*, page 6, lines 23 to 26). Applicant also describes various ways in which the compounds can be administered to a mammal in accordance with the claims and provides examples of effective dosing amounts, including for humans (*see e.g.*, page 11, lines 6 to 14). Applicant also, via reference to US 5,565,483, discloses useful formulations, that can be administered in the methods of the present invention.

In addition to the extensive teachings in the specification, it is noted that one skilled in the art would know how to confirm that the compounds of the present invention are effective in treating the gastrointestinal conditions recited in the claims. For example, U.S. Patent No. 6,596,759 discloses methods for establishing the usefulness of a compound for treating irritable bowel syndrome (*see e.g.*, example 1, attached). Thus, it is respectfully submitted that Claims 1 to 13 fully comply with the enablement requirement of Section 112, first paragraph as one skilled in the art would be able to make and use the full scope of the claimed invention without undue experimentation.

The Office Action seems to heavily base the present rejection on the fact that there are no working examples directed to gastric motility, and that there is no direction provided in the specification to treat any condition involving tissue *other* than ileum with any compound of the formula of claim 1. Applicant respectfully disagrees with this analysis as Claims 1 to 13, as amended, are directed to conditions that can be related to the intestines, such as for example, ileum tissue. In this regard, Claims 1 to 9 relate to treatment or inhibition of gastrointestinal conditions associated with at least one of irritable bowel syndrome, Crohn's Disease, colitis, diarrhea, abdominal pain associated with diarrhea, postprandial urgency, postprandial accentuation of diarrhea or abdominal pain, or nonulcer dyspepsia. Claims 10 to 13 relate to methods of inhibiting or controlling anal incontinence, or inhibiting or controlling defecation in a mammal. It is respectfully submitted that in view of the above amendments to the claims, one skilled in the art would be able to make and use Applicant's invention without undue experimentation.

Additionally, it is emphasize that nothing in Section 112, first paragraph, requires an Applicant to provide data in the specification to convince a person skilled in the art that the assertions in the specification are correct. In fact, case law holds that a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to

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be patented *must be taken as in compliance with the enabling requirement of the first paragraph of Section 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.*" See e.g., *Fiers v. Revel*, 25 USPQ2d 1601, 1607 (Fed. Cir. 1993). Here, there is no reason to doubt nor has the office action provided reasons to doubt the statements contained in the specification concerning the effectiveness of the methods of the present invention for treating the gastrointestinal conditions recited. Thus, the claims, as amended, fully comply with Section 112, first paragraph.

In view of the foregoing remarks, Applicant respectfully submits that Claims 1 to 13 fully comply with the requirements of Section 112, first paragraph. Accordingly, Applicant respectfully requests that the rejection under Section 112, first paragraph be withdrawn.

CONCLUSION

Applicant respectfully requests entry of the present amendment and withdrawal of all outstanding objections and rejections. Early and favorable notification of allowance of all pending claims is earnestly requested.

Respectfully Submitted,

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